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UNITED STATES COURTS OF APPEALS

FOR THE SIXTH CIRCUIT

JULIA GARCIA,

Plaintiff-Appellant,

v.

WYETH-AYERST LABORATORIES,

Defendant-Appellee.

No. 03-1712

Appeal from the United States District Court
for the Eastern District of Michigan at Bay City.
No. 01-10002—David M. Lawson, District Judge.

Argued: August 5, 2004

Decided and Filed: October 7, 2004

Before: KENNEDY, SUTTON, and COOK, Circuit Judges.

COUNSEL

ARGUED: John J. Schutza, WORSHAM & VICTOR, Southfield, Michigan, for Appellant. Shana J. Long, SHOOK, HARDY & BACON, Kansas city, Missouri, for Appellee. **ON BRIEF:** Richard B. Worsham, WORSHAM & VICTOR, Southfield, Michigan, for Appellant. Shana J. Long, Michael L. Koon, SHOOK, HARDY & BACON, Kansas city, Missouri, Scott L. Gorland, PEPPER HAMILTON, Detroit, Michigan, for Appellee.

OPINION

KENNEDY, Circuit Judge. Plaintiff Julia Garcia appeals the district court order granting summary judgment to Defendant Wyeth-Ayerst Laboratories in this drug product liability case on the basis of a statutory immunity provided in MICH. COMP. LAWS § 600.2946(5). Plaintiff argues that the district court erred in failing to declare the statute unconstitutional on the grounds that (1) it has been impliedly preempted by the federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.*, in violation of the Supremacy Clause, (2) it has interfered with her fundamental right of access to the courts and her Seventh Amendment right to a jury trial, and (3) it violated the Due Process Clause by depriving her of the right to use a traditional common law tort remedy as a means of seeking redress for her injuries. Finding no error in the district court's decision, we affirm.

BACKGROUND

In September of 1997, Plaintiff was treated for persistent pain in her neck and shoulders by her physician. To alleviate her pain, her physician gave her multiple prescriptions for Duract, a non-steroidal, anti-inflammatory prescription medication manufactured by Defendant. The medication had been approved for use earlier that year by the United States Food and Drug Administration ("FDA"). The medication, however, caused liver failure and Plaintiff was required to undergo a liver transplant in 1998 to save her life. Plaintiff sued Defendant for making and selling an unsafe drug, and she seeks compensation for her injury, reimbursement for past medical expenses, and future medical expenses including a likely additional liver transplant. Defendant has since voluntarily withdrawn the drug from the market. The district court granted Defendant's motion for summary judgment and dismissed the case on the basis of Michigan's products liability statute that immunizes drug manufacturers from liability under certain conditions. The present appeal followed.

ANALYSIS

Michigan law governs this diversity action. *Westfield Ins. Co. v. Tech Dry, Inc.*, 336 F.3d 503, 506 (6th Cir. 2003). The State of Michigan has adopted a drug products liability statute that immunizes drug manufacturers from liability from damages in suits contending that their drug was defective or unreasonably dangerous "if the drug was approved for safety and efficacy by [the FDA], and the drug and labeling were in compliance with [the FDA's] approval at the time the drug left the control of the manufacturer or seller." MICH. COMP. LAWS § 600.2946(5). The immunity is subject to two exceptions: (1) if the manufacturer intentionally withheld or misrepresented material information concerning the drug that it is required to be submitted under the Food and Drug Cosmetics Act and the drug would not have been approved, or the FDA would have withdrawn approval if the information was accurately submitted to the FDA, or if the manufacturer bribed an FDA official or employee to secure the drug's approval, MICH. COMP. LAWS § 600.2946(5)(a) & (b); and (2) if the offending drug was sold after the FDA withdrew approval or ordered the drug removed from the market, *id*.

In prior unrelated litigation, the Michigan Court of Appeals had held that this statute was repugnant to the Michigan Constitution because it impermissibly delegated legislative authority to the FDA as the final arbiter of drug safety in Michigan. *Taylor v. Gate Pharms.*, 639 N.W.2d 45 (Mich. Ct. App. 2001). The Michigan Supreme Court overturned that ruling holding that:

> MCL 600.2946(5) is a statute that refers to factual conclusions of independent significance, i.e., the FDA conclusion regarding the safety and efficacy of a drug, that once made causes, at the Michigan Legislature's direction, Michigan courts to find as a matter of law that the manufacturer or seller acted with due care.

Taylor v. Smithkline Beecham Corp., 658 N.W.2d 127, 134 (Mich. 2003). It concluded that the statute's linking of dangerousness to the FDA's complex and detailed approval process is nothing more than an incorporation of common standards, such as weights and measures or the time of day, which are also determined by federal agencies. According to the Michigan Supreme Court, therefore, the statute is valid under the Michigan Constitution. Plaintiff in this case, however, challenges the applicable statute under the *federal* constitution. As the district court properly noted, a federal court evaluating the statute's validity under the federal constitution is not bound by a state court's evaluation of the same statute under the state constitution. *Garcia v. Wyeth-Ayerst Labs.*, No. 01-10002-BC, slip op. at 3 (E.D. Mich. May 19, 2003) (citing *Barden Detroit Casino, L.L.C. v. City of Detroit*, 230 F.3d 848 (6th Cir. 2000)). Before the district court, Plaintiff argued that the Michigan statute is unconstitutional because (1) it had been impliedly preempted by the FDCA and therefore runs afoul of the Supremacy Clause, (2) it interferes with Plaintiff's fundamental right of access to the courts and her Seventh Amendment right to a jury trial, and (3) it violates the Due Process Clause by depriving her of the right to use a traditional common law tort remedy as a means

of seeking redress for her injuries.[1] For the reasons stated below, we agree with the district court that Plaintiff's arguments are without merit.

A. Implied Preemption

Plaintiff argued before the district court that Section 600.2946(5) conflicts with and is impliedly preempted by federal law because it requires one to prove fraud on the FDA as part of her cause of action against Defendant. She cannot prove fraud on the FDA because such claims are preempted by federal law and, thus, cannot bring herself within the exceptions. The district court agreed with Plaintiff that the fraud-on-the-FDA exception to the general statutory immunity was preempted by federal law but held that it could sever the offending exception and uphold the general statutory immunity in light of an explicit severability provision in MICH. COMP. LAWS § 8.5.

In general, a federal law may preempt a state law in any of the following three scenarios. First, a federal statute may expressly preempt the state law. *Gibson v. Am. Bankers Ins. Co.*, 289 F.3d 943, 948 (6th Cir. 2002). Second, a federal law may impliedly preempt a state law. *Id.* at 948-49. Third, preemption results from an actual conflict between a federal and a state law. *Id.* at 949. Since neither express preemption nor an actual conflict is present in this case, we are concerned solely with the question of implied preemption. As this Court has explained:

> Implied preemption occurs if a scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, if the Act of Congress touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject, or if the goals sought to be obtained and the obligation imposed reveal a purpose to preclude state authority.

Id. (citations omitted). As the district court properly noted, in "analyzing implied preemption, a court must begin with the assumption that a state law is valid and should be reluctant to resort to the Supremacy Clause." *Garcia v. Wyeth-Ayerst Labs.*, No. 01-10002-BC, slip op. at 7 (E.D. Mich. May 19, 2003) (citations omitted).

The United States Supreme Court has expressly considered the question of a state common law fraud-on-the-FDA tort claim and found that it was impliedly preempted by the FDCA and the Medical Device Act ("MDA"), 21 U.S.C. §§ 360e(b)(1)(A) & (B). *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 350 (2001) (explaining that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives.") This case, however, presents a somewhat different legal regime from the one invalidated in *Buckman*. The Michigan legislature has provided a general immunity for drug manufacturers with a specific exception for circumstances involving, *inter alia*, fraud on the FDA[2] rather than a specific cause of action for fraud on the FDA. This

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[1] On motion for summary judgment, the district court held that Plaintiff had submitted no evidence supporting its claims of bribery or misrepresentation to the FDA, nor any evidence that the withdrawal of Duract was precipitated by the FDA or based on any provable misconduct by Defendant. Plaintiff has not appealed that determination. Therefore, Plaintiff can only succeed in this action if we find that the two exceptions are unconstitutional and that the offending exceptions cannot be severed from the general immunity provision, thereby invalidating the general immunity provision and stripping Defendant of its statutory protection.

[2] The statute provides, in relevant part:

(5) In a product liability action against a manufacturer or a seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller....This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the

difference, however, is immaterial in light of *Buckman*. As the district court properly found, "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Garcia v. Wyeth-Ayerst Labs.*, No. 01-10002-BC, slip op. at 8 (E.D. Mich. May 19, 2003).

Having concluded that M.C.L. § 600.2946(5)(a) and (b) were unconstitutional, the district court had to consider what effect that conclusion had on the rest of M.C.L. § 600.2946(5). It is unclear whether the district court concluded that the offending subsections can simply be severed from the rest of the section, giving drug manufacturers a full immunity from state-law lawsuits in the State of Michigan as long as they complied with the FDA's requirements and the drug had been approved by the FDA, or whether it concluded that in view of the preemption "the exceptions can only be triggered by a finding by the FDA that a drug manufacturer committed fraud or bribed an FDA official in order to obtain approval of a drug." Appellee's Br. at 18.

It is one thing, however, to say that *Buckman* applies to the exemptions contained in Michigan Compiled Laws § 600.2946(5); it is quite another to say that *Buckman* preempts these exemptions in all of their applications. Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of *state court* findings of fraud on the FDA. Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*. But the same concerns do not arise when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process. *Cf. Buckman*, 531 U.S. at 351 ("[F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court."). Thus, in this setting, it makes abundant sense to allow a State that chooses to incorporate a federal standard into its law of torts to allow that standard to apply when the federal agency itself determines that fraud marred the regulatory-approval process. In the final analysis, the exemptions are invalid as applied in some settings (*e.g.*, when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (*e.g.* claims based on federal findings of bribery or fraud on the FDA).

Having concluded that Michigan Compiled Laws § 600.2946(5)(a)&(b) are unconstitutional in some settings – including plaintiff's own suit (as she alleged bribery and fraud on the FDA but did not offer any federal findings) – we now face the issue urged upon us by the plaintiff: Does the preemption of these exemptions in some settings requires us to invalidate § 600.2946(5) in its entirety? We do not think so.

The Michigan Legislature has provided a general severability clause that applies to all its enactments. The clause provides:

> In the construction of the statutes of this state the following rules shall be observed unless such construction would be inconsistent with the manifest intent of the legislature, that is to say: If any portion of an act or the application thereof to any person or circumstances shall be found to be invalid by a court, such invalidity shall not affect the remaining portions or applications of the act which can be given effect without the invalid portion or application . . ., and to this end acts are declared to be severable.

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following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . ., and the drug would have not been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

(b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

MICH. COMP. LAWS § 600.2946(5).

Mich. Comp. Laws § 8.5. *See also Maki v. East Tawas*, 188 N.W.2d 593, 596 (Mich. 1971) (upholding the remainder of the enacted law because it is "otherwise complete in itself and capable of being carried out without reference to the unconstitutional" section). The question, accordingly, is whether the Michigan Legislature would have preferred the situation where drug manufacturers would enjoy immunity in the absence of a federal finding of bribery or fraud on the FDA, or the situation urged by the Plaintiff where drug manufacturers would enjoy no immunity at all. As we explained on an earlier occasion, the law remaining after an invalid portion of the law is severed will be enforced independently "unless the invalid provisions are deemed so essential, and are so interwoven with others, that it cannot be presumed that the legislature intended the statute to operate otherwise than as a whole." *Moore v. Fowinkle*, 512 F.2d 629, 632 (6th Cir. 1975).[3]

We find that Plaintiff has failed to persuade us that the district court erred as a matter of law, and that given a choice between immunity absent a finding of bribery or fraud by the Federal Government and no immunity, the Michigan Legislature would prefer the former option. First, it appears that the Michigan legislature was concerned that unlimited liability for drug manufacturers would threaten the financial viability of many enterprises and could add substantially to the cost and unavailability of many drugs. *See generally* State Fiscal Agency, Revised Bill Analysis, S.B. 344 & H.B. 4508 (Mich. 1996). Second, and most importantly, severing the preemption exemptions will not give license to drug manufacturers to use bribery or fraud as a means of obtaining FDA approval, then rely on that approval as a shield from products liability: it will merely place responsibility for prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than state courts.

B. Access to Courts and the Right to a Jury Trial

Plaintiff also argues that her rights to have access to courts and a jury trial have been violated by her complete inability to obtain relief for her injury. We find it unnecessary to add anything to the thoughtful analysis provided by the district court on this question:

> Although a right-of-access case can be established when a person can prove that a state's judicial process does not provide an adequate procedure to remedy an alleged wrong, *see Glover v. Johnson*, 75 F.3d 264, 268 (6th Cir. 1996) ("Access to the courts . . . encompasses all the means a defendant . . . might require to get a fair hearing from the judiciary on all charges brought against him or grievances alleged by him.") (citing *Gilmore v. Lynch*, 319 F. Supp. 105, 110 (N.D. Cal. 1970), *aff'd sub nom. Younger v. Gilmore*, 404 U.S. 15 (1971), such claims are generally recognized for civil litigants only in the context of spoliation of evidence or interference with filing a lawsuit. *See* [*Swekel v. City of River Rouge*, 119 F.3d 1259, 1263-64 (6th Cir. 1997)]. A cognizable claim can be made out "only by showing that the defendants' actions foreclosed [a potential litigant] from filing suit in state court or rendered ineffective any state court remedy [the litigant] previously may have had." *Ibid*. The argument that a state statute stiffens the standard of proof of a common law claim does not implicate this right.
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> In this case, the plaintiff does not allege that she was unable to gain access to court to litigate her claim. Rather, she contends in essence that Section 600.2946(5) requires too much, and that the immunity it grants to drug manufacturers is too broad. These allegations do not constitute a claim of denial of access to the courts.

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[3] Where possible, the Supreme Court "interprets congressional enactments to avoid raising serious constitutional questions," *Cheek v. United States*, 498 U.S. 192 (1991) (citations omitted). The Michigan courts adhere to a similar principle. "A legislative enactment can be held to be facially invalid only if there are no factual circumstances under which the provision could be constitutionally implemented." *Gera v. Maxwell, et al.,* 456 Mich. 704 (1998) (citing *United States v. Salerno*, 481 U.S. 731, 739 (1987) n.15, *Pigorsh v. Fahner*, 386 Mich. 508 (1972) at 509 (we are bound, if possible, to construe statutes as to give them validity and a reasonable interpretation)).

Garcia v. Wyeth-Ayerst Labs., No. 01-10002-BC, slip op. at 19-20 (E.D. Mich. May 19, 2003). Plaintiff has failed to set forth any legally binding precedent that would warrant a reversal of the district court's opinion in this respect.

C. Due Process

Plaintiff finally challenges the district court's finding that the abolition of her cause of action does not violate the Due Process Clause. Plaintiff's argument is without merit. As this Court has previously stated,

> Legislatures do not violate federal due process rights by creating statutes of repose that prevent causes of action from accruing. A litigant has no vested property right in a cause of action until it accrues. The United States Supreme Court has held that due process does not prohibit the abolition of causes of action[. Those] cases have clearly established that a person has no property, no vested interest, in any rule of the common law [,and that t]he "Constitution does not forbid the creation of new rights, or the abolition of old ones recognized by the common law, to attain a permissible legislative object" despite the fact that otherwise settled expectations may be upset thereby.

Hartford Fire Ins. Co. v. Lawrence, Dykes, Goodenberger, Bower & Clancy, 740 F.2d 1362, 1367 (6th Cir. 1984) (citations omitted). The only question for us to consider is whether Section 600.2946(5) rationally furthers a legitimate state objective. On that point, we agree with the district court's finding that "the Michigan legislature acted within its authority when it granted immunity from liability to drug sellers and manufacturers who market their products after obtaining approval from the FDA." *Garcia v. Wyeth-Ayerst Labs.*, No. 01-10002-BC, slip op. at 14 (E.D. Mich. May 19, 2003).

CONCLUSION

For the reasons stated above, we affirm the district court's order granting summary judgment in favor of Defendant.